GEMORE TECHNOLOGY CO., LTD.

NOV 17 2004

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042559

1. Submitter's Identifications:
   GEMORE TECHNOLOGY CO., LTD.
   11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD.,
   Tan Shui, Taipei Hsien, Taiwan

   Contact:
   Boden S.P. Lai
   General Manager

   Date of Summary Preparation: August 29,2004.

2. Name of the Device:
   GEM-TWIN TENS Device/ Model GM3XY/Z, where X (8 or 9) means two different kinds of housing to mount any combination of Y and Z operation unit. And Y and Z may be the arbitrary combination of 0T/0E/0TE/0PP/0PE/2IF/3HV, where "0T" means TENS function. "0E" means EMS function, "0TE" means TENS and EMS combination function in one unit, "0PP" means preprogram TENS, "0PE" means preprogram EMS, "2IF" means IF TENS, and "3HV" means high voltage TENS..

3. Information of the 510(k) Cleared Device (Predicate Device): K032720, K032719 & K032994.

4. Device Description:

   The GEM-TWIN TENS series, including GM38Y/Z and GM39Y/Z(where Y and Z are any combination of 0T/0E/0TE/0PE/0PP/2IF/3HV), are transcutaneous electrical nerve stimulator used for pain relief and/or powered muscle stimulator by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the situation of patient.

   The GEM-TWIN TENS series, including GM38Y/Z and GM39Y/Z(where Y and Z are any combination of 0T/0E/0TE/0PE/0PP/2IF/3HV), consist mainly of three parts: the TWIN housing, stimulation generators, and electrode. The TWIN housing is the housing to mount any two stimulation units, and to provide the connection of supply power and stimulation lead wires. The stimulation generator generates the output current specified as the input of controller. The output electrodes transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief.

   The stimulation mode for GEM-TWIN TENS includes several different operation modes as mentioned on the comparison table. These operation modes are generated from the software control by using the microprocessor as its main control unit.

5. Intended Use:
   On the instruction manual of each model, the intended uses and contraindication are defined very clearly. Please see the information of instruction manuals in clause 7.6 of this submission document. In addition, the standard format for the statement of indications and contraindication for use are provided hereafter.

Indications For Use

510(k) Number (if known): K042559

Device Name: "GEM-TWIN TENS Device/ Model GM3XY/Z, where X (8 or 9) means two different kinds of housing to mount any combination of Y and Z operation unit. And Y and Z may be the arbitrary combination of 0T/0E/0TE/0PP/0PE/2IF/3HV, where "0T" means TENS function. "0E" means EMS function, "0TE" means TENS and EMS combination function in one unit, "0PP" means preprogram TENS, "0PE" means preprogram EMS, "2IF" means IF TENS, and "3HV" means high voltage TENS."

Indications For Use:

<1> If any one of "0T", "0PP", and/or "0TE" is mounted for Y or Z.

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

<2> If any one of "0E", and/or "0TE" is mounted for Y or Z.

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

<3> If any one of "0PE" is mounted for Y or Z.

- Relaxation of muscle spasms.

<4> If any "2IF" is mounted for Y or Z

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

<5> If any "3HV" is mounted for Y or Z

The device is an high voltage TENS device with TENS indications used for symptomatic relief and management of chronic intractable pain.

Prescription Use X OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6. Comparison to the 510(k) Cleared Device (Predicate Device):
   (1) The new model GM38Y/Z and GM39Y/Z (where Y/Z is equipped with any one of 0T/0E/0TE/0PE/0PP) are substantially equivalent to the GEMORE cleared model as mentioned in K032720.
   (2) The new model GM38Y/Z and GM39Y/Z (where Y/Z is equipped with 2IF) are substantially equivalent to the GEMORE cleared model as mentioned in K032719.
   (3) The new model GM38Y/Z and GM39Y/Z (where Y/Z is equipped with 3HV) are substantially equivalent to the GEMORE cleared model as mentioned in K032994.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

   In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions
   The GEM-TWIN TENS series, including GM38Y/Z and GM39Y/Z(where Y and Z are any combination of 0T/0E/0TE/0PE/0PP/2IF/3HV), have the same intended use and technological characteristics as the cleared device of the devices being modified(the models as mentioned in GEMORE previous cleared 510(K), K032720, K032719, and K032994). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Mr. Boden S.P. Lai
General Manager
Gemore Technology Co., Ltd.
11 Fl., No. 29-5, Sec. 2, Chung Cheng E. RD.
Tan Shui, Taipei Hsien, Taiwan

Re: K042559
Trade/Device Name: GEM-TWIN TENS Device/ Model GM3XY/Z
Regulation Number: 21 CFR 890.5850, 21 CFR 882.5890, and Unclassified
Regulation Name: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief, and Interferential Current Therapy device.
Regulatory Class: II and unclassified
Product Code: IPF, GZJ, and LIH
Dated: October 18, 2004
Received: October 20, 2004

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K042559

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The device is an high voltage TENS device with TENS indications used for symptomatic relief and management of chronic intractable pain.

Prescription Use X OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Mark N. Milhern

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) Number K042559